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08/981,310

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EXAMINER	
PORTNER, V	
ART UNIT	PAPER NUMBER
1645	22
DATE MAILED 09/18/00	

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☒ is extended to run 2mo or continues to run \_\_\_\_\_ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

- ☐ Applicant's response to the final rejection, filed \_\_\_\_\_ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- a. ☒ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
  - b. ☒ They raise new issues that would require further consideration and/or search. (See Note).
  - c. ☐ They raise the issue of new matter. (See Note).
  - d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: see attached

2. ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: none  
Claims objected to: none  
Claims rejected: 1-6, 8-10

However,

☒ Applicant's response has overcome the following rejection(s): none, the Amndt was not entered.

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because: see attached
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other 1449

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Claims 1-6 and 8-10 are pending.

***Status of Amendments After Final***

1. The Amendment After Final submitted April 27, 2000 has been entered.
2. The Amendment After Final submitted June 23, 2000 has been entered.

***Status of Claim rejections***

3. Claims 1, 3-5 remain rejected under 35 U.S.C. 102(e) as being anticipated by or in the alternative as being obvious over Birkenmeyer et al (US Pat. 5,667,974).
4. Claims 1, 3-5 are rejected under 35 U.S.C. 103(a) as being obvious over Nickerson et al (1992) or Delahunty et al (1995) or Kwok et al (1992) or Nilsson et al (1994)
5. Claims 1-6 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al in view of Dattagupta et al (US Pat. 4,78,111) and Ciechanover et al (US Pat. 5,384,255).
6. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendrickson et al for reasons of record.
7. Claims 6, 8-10 are rejected under 35 U.S.C. 112, first paragraph, as the method is not claimed using the essential reagents required for conducting the method.
8. Claims 8-10 remain rejected under 35 U.S.C. 112, second paragraph as not distinctly claiming Applicant's invention for reasons of record.

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*Response to Amendment*

9. It was evident to the examiner that the Amendment submitted June 23, 2000 was submitted in an effort to clarify the “conjugation” of reactants in the method. Specific reagents recited in claims 8-10 were deleted and the conjugation process recited in the base claim defined through the recitation of a “wherein” clause.

10. While the Amendment After Final may have addressed the meaning of the word “conjugation” recited in claim 6, it did not address the broad issues surrounding the claimed method. Specifically, the method of claim 6 does not recite the essential reagents needed to conduct the method. The rejection made under 35 U.S.C. 112, first paragraph was not resolved. In fact, with the deletion of the specific needed reagents from the dependent claims, the methods of claims 6-10 do not define methods steps that provide essential reagents for the amplification step.

11. The Amendment After Final was not entered as it would raise new issues. While possibly resolving one issue under 35 U.S.C. 112, 2nd paragraph, it would introduce new 112, 2nd problems.

a. The “conjugation” referred to in claims 8-10 and depends from claims 6-7, 6, or 8 respectively, lacks antecedent basis in the claims 6 and 7 from which they directly or indirectly depend.

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b. The oligonucleotide complementary to the conjugatable oligonucleotide recited in claim 8, and depends from claims 6 or 7 has not been provided in the method of claim 6.

c. It is not clear to the examiner that ligation and conjugation are one in the same. Claim 10, states that the conjugation occurs through ligation of the oligonucleotides. The addition of other reagents must be added for conjugation to occur after ligation of the two conjugatable oligos are ligated. These reagents have not been provided in the method.

12. For the above cited reasons, and the rejections made of record that were not obviated by the Amendment submitted June 23, 2000, the Amendment was not entered.

13. No showing of unexpected results has been made of record to overcome the prior art rejections made under 35 U.S.C. 103.

#### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. de la Monte et al (US Pat. 5,830,670) is cited to show a method of diagnosing Alzheimer's disease using multiple (3) monoclonal antibodies, one of which is immobilized on a solid

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phase and detection of the presence or absence of analyte is through immuno-polymerase chain reaction (see claims 1-6).

16. Shi et al (US Pat. 5,919,626) is cited to show the use of immobilized and unimmobilized affinity reagents to detect a macromolecule.

17. Landegren et al (US Pat. 4,988,617) is cited to show an assay and kit that uses reagents, one of which is immobilized and the others are not immobilized for the detection of a macromolecule.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.


The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 30, 2000

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER